

Atty. Dkt. No. 039386-0220 (PF-0561-USN)
Appln. No. 09/744,196

REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 3 was amended in the Response submitted January 6, 2005, however it was inadvertently misidentified as "original." Further, the claim was presented in clean form, without showing the amendments to the claim language. Pursuant to the telephone interview with the Examiner on June 2, 2005, claim 3 is identified herein as "previously presented" and shows the amendments to the claim language as submitted in the previous response. Those amendments incorporated the language from cancelled claim 1, from which claim 3 had previously depended.

Claims 4, 5, and 8 are amended. The amendments contained herein do not contain any new matter as they are fully supported by the specification and the claims as originally filed. Support for the amendments to each claim can be found in the specification as follows.

Claim 4 – see the specification at page 15, lines 3-6.

Claim 5 – see the specification at page 16, lines 18-20.

Claim 8 – see the specification at page 15, lines 6-10.

It is respectfully submitted that entry of the amendments submitted herewith is proper because these amendments place the present application in condition for allowance or at a minimum, in better condition for appeal. Accordingly, entry of the amendments submitted herewith is respectfully requested.

Upon entry of this Amendment, claims 3-11 will remain pending in the application. A detailed listing of all claims that are, or were, in the application, irrespective of whether a particular claim remains under examination in the application, is presented, beginning on page 2 of this paper under "Listing of Claims," with an appropriate defined status identifier.

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II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Claim Rejections – 35 U.S.C. § 101

The rejection of claims 3-11 under 35 U.S.C. § 101 for allegedly not being supported by either a specific, substantial and credible asserted utility, or a well established utility respectfully traversed for at least the reasons of record.

Specifically, it is respectfully submitted that the application supports the use of MACP-2 for detecting and/or treating cell proliferative diseases, such as prostate cancer, because MACP-2 is useful as a prostate cancer marker. For example, the application teaches that MACP-2 expression is correlated with proliferative disorders, particularly prostate cancer. As stated in the previous response, the application teaches that MACP-2 was isolated from a cDNA library (PROSNOT15) derived from a prostate cancer tumor sample (see Table 1, and Table 4 for a description of the library). Furthermore, the nucleotide sequence encoding MACP-2 (SEQ ID NO:7) was found in 71.4% of cDNA libraries that were proliferative in nature (see Table 3). These data suggest a link between MACP-2 and cell proliferative disease, and in particular prostate cancer.

These data are further supported by data from the literature in which the polynucleotide sequence encoding MACP-2 was found to be down-regulated in prostate cancer. In this report, Wissmann et al. (J. Pathol 201(2):204-12, 2003) show that expression of the polynucleotide encoding MACP-2 (termed WIF1 in this report) is down-regulated at the RNA level in 64% of primary prostate cancers. These data further support the use of polynucleotides encoding MACP-2 as markers in prostate cancer.

Based on the above, the specification provides a credible utility for the claimed polynucleotides. Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

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b. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph (Enablement)

The rejection of claims 3-11 under 35 U.S.C. § 112 first paragraph for an alleged lack of enablement is respectfully traversed. Specifically, in rejecting claims 3-11 under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a well-established or a disclosed specific and substantial credible utility, the Examiner asserts that "one skilled in the art clearly would not know how to use the claimed invention" (Office Action at page 3, line 17).

Based on the arguments in the preceding section, it is respectfully submitted that the application supports a credible utility for the claimed polynucleotides and therefore, the rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement has been rendered moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

c. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph (Written Description)

The rejection of claims 4 and 8 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description is respectfully traversed for at least the reasons already of record.

Applicants respectfully disagree with the Examiner's assertion that "the specification does not identify any particular portion of the structure that must be conserved" (Office Action at 5, lines 21-22). Contrary to the Examiner's assertion, it is respectfully submitted that the specification does disclose portions of the structure of MACP-2 which must be conserved. Furthermore, based on the present disclosure, the requirements of the claim, and that which was known in the art, one of skill in the art would understand how many amino acid residues outside of the regions which must be conserved could be substituted as well as the nature of those substitutions.

The specification, as discussed in the previous response, provides disclosure of signature sequences and motifs that would be readily recognized by those of skill in the art as portions of

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the sequence which must be conserved. See for example, Table 2 at page 51 where the following signature sequences are disclosed:

Signature sequences: G285-S292, C198-C209, C230-C241, C262-C273, C294-C305, C326-C337

Potential glycosylation sites: N88, N245

Potential phosphorylation sites: T319, S105, T215, S362, Y377

This information informs the skilled person of the pertinent portions and characteristics of the polypeptide sequence depicted in SEQ ID NO:2 which should be conserved.

Furthermore, the polypeptides embraced by claim 4 as presently amended, require that those polypeptides share "95% sequence identity" with SEQ ID NO:2. Therefore, a polypeptide as contemplated by this claim is one that can accommodate no more than 19 distinct amino acid substitutions (SEQ ID NO:2 contains 379 residues). Armed with this information, and the signature sequences provided above, one of skill in the art would know which residues were amenable to substitution (i.e., by excluding the residues comprising the signature sequences) and how many substitutions one could make.

Finally, those of skill in the art would understand the nature of the substitutions one could make. Indeed, just as there exists degeneracy of the DNA code, there similarly exists amino acid substitutions that can be made to a polypeptide, which are conservative in nature and which do not alter the basic properties of the residue that is replaced. For instance, a glycine or a serine residue can replace an alanine residue. Applicants disclose at page 13, lines 26-28, what "conservative changes" are and that computer programs well known in the art (e.g., Lasergene) can assist the skilled artisan in determining which residues may be substituted within a polypeptide sequence without disrupting function.

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Analogous arguments can be made for claim 8 which is directed to polynucleotide variants having at least 95% sequence identity to SEQ ID NO:7 (the polynucleotide encoding SEQ ID NO:2). Using routine methods of sequence comparison, one of skill would readily recognize a sequence having a minimum of 95% identity to SEQ ID NO:7. Further, the structural attributes described above would also apply to the polynucleotide regions encoding those attributes.

Based on the above, the written description requirement is fully satisfied for the scope of claims 4 and 8, as presently amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

d. Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

The rejection of claim 5 under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite with regard to the use of the phrase "stringent conditions" is respectfully traversed for at least the reasons already of record.

Specifically, it is respectfully submitted that claim 5 is clear as written because the phrase "stringent conditions" is described in the specification and is well-known to those of skill in the art. As stated in the previous response, there is ample description in the specification regarding the many parameters involved in hybridization conditions, including how to adjust those parameters to increase or decrease stringency. Furthermore, several references are cited in the specification which provide additional discussion of stringent hybridization conditions. Finally, those of skill in the art would readily understand this phrase and further, would recognize that stringency conditions are routinely optimized to achieve a desired degree of stringency.

However, in efforts to reduce the issues and expedite prosecution, claim 5 has been amended herein to define Applicants' invention with greater particularity. Specifically, the amended claim requires that "stringent conditions" comprise "37°C in 500 mM NaCl, 50 mM

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trisodium citrate, 1% SDS, 35% formamide, and 100 µg/ml denatured salmon sperm DNA (ssDNA).”

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

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CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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Enclosure: *Wissman, et al. (J. Pathol., 201(2):204-12, 2003)*